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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,021	02/26/2004	Kristin Feeley	12712/46101	2923
23838	7590	09/14/2005	EXAMINER	
KENYON & KENYON 1500 K STREET NW SUITE 700 WASHINGTON, DC 20005			WILLIAMS, CATHERINE SERKE	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 09/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/786,021

Applicant(s)

FEELEY ET AL.

Examiner

Catherine S. Williams

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 6,9,11,13 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,8,10,12 and 14-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/9/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention:

- a) Figs 1A-1C,
- b) Fig 2,
- c) Fig 3, and
- d) Fig 4.

Furthermore if species (a) is selected then a further sub-species election is required of one of the sub-species below.

- a) Fig 5A,
- b) Fig 5B, and
- c) Fig 5C.

Figures 6A-8 are considered generic to all the above species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-2 and 14-17 are considered generic.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Doug Ringel on 9/6/05 a provisional election was made with traverse to prosecute the invention of species (a) and subspecies (a). Upon review of the claims by the examiner, it was concluded that the claims readable on the elected species are claims 1-5,7-8,10,12 and 14-19. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6,9,11,13 and 20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 10 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Tan (USPubN 2004/0230162). Tan discloses an antimicrobial iodine bearing intervention rod (60), a hub (90), and a delivery tube (100) where the hub ejects the rod from the tube. See figures 1a-2. The tube has a low durometer thermoplastic polyurethane and is non-permeable to iodine. See paragraph 0024-1128 and 0034.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 8, 12 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hochman (USPN 6,726,658) in view of Roby (USPubN 2003/0236552). Hochman discloses an intervention rod (86), a hub (50), and a delivery tube (12) where the hub ejects the rod from the tube. See figures 1-4. The tube has a continuous slit longitudinal partition (24) and hub opening (32). The hub is disposed within the tube and the hub has an extension arm (100) extending through the hub opening. See figure 7. The arm and hub have a tapered connection point that enables removal (106). See 7:20+. The hub has an aperture. See figure 8. A valve (22) is coupled to an open end of the delivery tube. The method steps of coupling, forming, and disposing are considered inherent in order to properly make and use the device as disclosed.

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Hochman meets the claim limitations as described above but fails to include the rod being an antimicrobial bearing device. However, Roby discloses a siliconized surgical needle that includes iodine. The needle is designed for optimal ease of entry into the patient to reduce patient pain.

At the time of the invention, it would have been obvious to incorporate the teaching of a siliconized needle with iodine into the invention of Hochman. Both devices are analogous in the art of percutaneous administration into a patient; therefore, a combination is proper.

Additionally, the motivation is provided in that Roby teaches an enhanced design for administering a needle to a patient with reduced pain and the incorporation of the needle into Hochman would have been in order to provide the patient with an enhanced needle design for reduced pain.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hochman in view of Roby. Hochman in view of Roby meets the claim limitations as described above but does not teach a perforated partition.

At the time of the invention, it would have been an obvious design choice to make the slit of Hochman as a perforated slit. Applicant has failed to establish that the perforated slit provides an advantage or solves a stated problem. Furthermore, one would expect a continuous slit or a perforated slit to perform equally well considering that either slit would enable the rod to be advanced toward a patient.

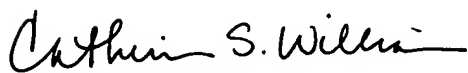
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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Catherine S. Williams
September 12, 2005